Award Number: W81XWH-10-1-0924

TITLE: A Civilian/Military Trauma Institute: National Trauma Coordinating Center

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CONTRACTING ORGANIZATION:
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REPORT DATE: October 2012

TYPE OF REPORT: Addendum to Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

Approved for public release; distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
1 October 2012	Addendum to Final	24-Sept-11 to 23-Sept-12

A Civilian/Military Institute-Trauma Care, Research and Training	**5a. CONTRACT NUMBER** W81XWH-10-1-0924
	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S) Ronald M. Stewart, M.D. Monica Phillips M.S.N stewartr@uthscsa.edu	**5d. PROJECT NUMBER**
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Texas Health Science Center 7703 Floyd Curl Drive San Antonio, TX 78229	**8. PERFORMING ORGANIZATION REPORT NUMBER**
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army MRMC Fort Detrick, Maryland 21702-5012	**10. SPONSOR/MONITOR'S ACRONYM(S)**
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited)

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this grant is to support a national coordinating center for trauma research funding, and provide a forum for dissemination of trauma research information to the trauma community. The infrastructure/process is streamlined and efficient leading to the selection of research projects based on a solid scientific, peer review of submitted research proposals. The selected research projects are well on their way to achieving their objectives. The NTI annual Trauma Symposium was held August 30 - September 1, 2010.

15. SUBJECT TERMS

Trauma, ICU, education, research, training, analysis, practice

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. R E	**b. ABSTRACT** U	**c. THIS PAGE** U	UU	**18**	USAMRMC
					19b. TELEPHONE NUMBER *(include area code)*

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INTRODUCTION

The University of Texas Health Science Center at San Antonio (UTHSCSA) proposed to utilize $2,101,000K in congressional funding to work collaboratively with National Trauma Institute (NTI) to build on the establishment of NTI as a national coordinating center for trauma research funding. In addition to this, a forum for dissemination of trauma research information was provided for the trauma community through the NTI Annual Trauma Conference. A one year no-cost-extension was approved September 2011. A second, one year no-cost-extension was approved September 2012 to complete the funded research.

Body

Statement of Work

A. The contractor will support a national coordinating center for trauma research funding.

1. Requests for proposals (RFP) based on areas of scientific merit in trauma and emergency or critical care will be prepared and issued.
2. NTI Board Science Committee will score proposals according to scientific merit, clinical impact and ability to perform.
3. NTI Board will update trauma research subject areas based upon the basis of impact on survival or care of patients, existing funding, and funding availability annually.
4. Perform Award management and compliance to include all appropriate USAMRMC HRPO requirements.
5. Provide research funding for proposals that seek to address areas of urgent need in the treatment of trauma.
    a) Timing and Mechanism of Traumatic Coagulopathy, PI - Mitchell Cohen, MD, University of California, San Francisco.
    b) Comparative Effectiveness of Clinical Care Processes in Resuscitation and Management of Moderate to Severe Traumatic Injuries. PI - Shahid Shafi, MPH, MD, FACS, Baylor Research Institute
    c) Characterization of the Effects of Early Sex-Hormone Environment Following Injury, PI - Jason L. Sperry, MD, MPH, University of Pittsburgh
    d) Vasopressin Supplementation during the Resuscitation of Hemorrhagic Shock PI - Carrie Sims, MD, MS, University of Pennsylvania

B. The contractor will provide a forum for dissemination of trauma research information to the trauma community.

1. NTI Annual Trauma Symposium was held August 2010.
2. Symposium program focused on dissemination of research information to the trauma community
3. Breakouts included; Trauma/Critical Care, Orthopedic Trauma, Emergency Care, Trauma Nursing, Oral maxillofacial Trauma, Trauma Mental Health, Neurosurgery, Craniofacial, Anesthesiology, and Burn Surgery.

A. National Coordinating Center for Trauma Research Funding:

Research Funding For Proposals that Address Areas of Urgent Need in the Treatment of Trauma

Project 1:

Project Title: Timing and Mechanism of Traumatic Coagulopathy
PI Name: Mitchell Cohen, MD
PI Institution: University of California, San Francisco
Status: Approved HRPO Log#: A-16375.3a
Participating centers include:

a) UTHSC-Houston, Center for Translational Injury Research (CeTIR), Dr. Bryan Cotton. HRPO Log# A-16375.b
b) University of California, Berkeley, Adam Hubbard, PhD. HRPO Log # A-16375.c

The period of performance for this subaward is February 11, 2011 to February 10, 2013. A one year NCE was approved on 1/18/2012 to complete data analysis, and allow for publication preparations.
This protocol's renewal was approved by the UCSF IRB on 5/30/2012 and by HRPO on 6/26/2012.

This project is currently in the third quarter of year two. As of the last report dated 6/22/2012, sample collection continues at both UCSF and UTHSC-Houston beyond initial recruitment goals. The Principal Investigator believes that due to the infrastructure being in place and the high value of the samples additional sample collection will strengthen the merit of the project. Measurement of all samples continues.

An abstract "The Principal Components of Acute Traumatic Coagulopathy" was presented at the 2012 Annual American Association for the Surgery of Trauma (AAST) meeting in September 2012, in Kauai, Hawaii (Appendix A).

Project 2:

Project Title: Comparative Effectiveness of Clinical Care Processes in Resuscitation and Management of Moderate to Severe Traumatic Injuries
PI Name: Shahid Shafi, MPH, MD, FACS
PI Institution: Baylor Research Institute
Status: Approved HRPO Log#A-16375.2a
Participating centers include:

a) University of Texas Health Science Center, Houston, Dr John Holcomb, Approved HRPO Log#16375.2c
b) University of California at Los Angeles HRPO Log# A-16375.2d, Approved
c) Massachusetts General Hospital HRPO Log# A-16375.2e, Approved

The period of performance for this award is December 1, 2010 to December 31, 2012 which includes a NCE to complete data analysis.

This protocol's renewal was approved by Baylor IRB on 2/22/2012 and HRPO on 4/17/2012.

During the past year, the two additional sites obtained site/local IRB approval and HRPO approval. All sites were able to complete enrollment as projected and data collection was completed at all sites on 6/11/2012. Data analysis was completed at Massachusetts General Hospital and UTHSC-Houston on June 30, 2012, and at UCLA in August 2012. Further data analysis is required to fulfill all study specific aims. The NCE will also be utilized for preparation of manuscripts. A manuscript titled "Moving from "optimal resources" to "optimal care" at trauma centers" was published in the Journal of Trauma (Appendix B).

Project 3:

Project Title: Characterization of the effects of early sex-hormone environment following injury
PI Name: Jason L. Sperry, MD, MPH
PI Institution: University of Pittsburgh (Single Center study)
Status: Approved HRPO Log#: A-16375.1

The period of performance for this award is December 7, 2010 to December 31**,** 2012, including two 6 month NCEs which were granted to allow for completion of subject enrollment and analysis.

This protocol's renewal was approved by Pittsburgh IRB on 3/15/2012 and HRPO on 5/14/2012.

The trial has been enrolling since 2/1/11, and this site has successfully screened 2800 patients and consented and enrolled 293 patients over the last 19 months. Coagulation measurements have been performed and serum samples are being currently measured for sex hormone concentration and cytokine analysis. Data entry for outcomes of interest are being recorded prospectively including resuscitation requirements, nosocomial infection, multiple organ failure, and mortality, along with important injury characteristics for multivariate analysis. Over 270 patients have completed outcome data. The site will continue trial enrollment with a target of 320 patients through November 2012, to increase the analysis power. Complete sex hormone and cytokine measurements will be performed, with continued prospective data collection for outcomes and injury characteristics. The PI anticipates completing data collection by mid January, with analysis completed the following quarter.

Project 4:

Project Title: Vasopressin Supplementation during the Resuscitation of Hemorrhagic Shock
PI Name: Carrie Sims, MD, MS
PI Institution: University of Pennsylvania
Status: HRPO Log# A-16375.4, currently under review by the Secretary of the Army for waiver of informed consent.

Current Progress:

Dr Sims' project is in the process of obtaining HRPO approval. This project utilizes the Exception from Informed Consent and Community Consultation (10USC980). The project will start once HRPO approval and subcontracting is completed.

As of October 5, 2012 per correspondence from the Office of Research Protections (ORP) Director, Dr. Laura Brosch: This project's second level of review was completed and all queries addressed satisfactorily. The project was anticipated to arrive at the Office of the Surgeon General (OTSG) by 10/5/2012. As Dr. Brosch explained, the timeline estimate is as follows: 2 weeks at the Office of the Surgeon General—legal, ethical, administration; 2 weeks at Headquarters, Department of the Army (HQDA) staffing to include HQDA legal; and then one week from HQDA to the Secretary of the Army.

B. Provide a Forum for Dissemination of Research Outcomes to the Trauma Community.

The 16th National Trauma Institute Annual Symposium was held August 30-September 1, 2010.

This task is complete.

Table 1: Overall Award Milestones

Milestone	Planned Date	Actual Date	Projected Completion Date	Status
Grant Awards Announced	Q1	3/31/10	N/A	Complete
Contracting	Q1	10/5/2010	January 2013	3 of 4 sites contracted (remaining site is awaiting HRPO approval with waiver from the Secretary General of the Army)
Compliance Management	Q1-ongoing	10/5/2010 – ongoing	N/A	Ongoing
Cost reimbursement	Milestone-based, associated with reporting		August 2013	Ongoing
Reporting	Quarterly & Annually	All quarters	October 2013	Ongoing
2010 Symposium Management/ Organization	All quarters	All quarters	N/A	Complete
Symposium held	August 2010	8/31/2010	N/A	Complete

Key Research Accomplishments

None at this time

Reportable Outcomes

1. Matthew Kutcher, Adam Ferguson, Mitchell Jay Cohen*, M.D. The Principal Components of Acute Traumatic Coagulopathy. Oral presentation at 2012 AAST annual meeting in September 2012, in Kauai, Hawaii (Appendix A).
2. Shafi S, Rayan N, Barnes S, et al. Moving from "optimal resources" to "optimal care" at trauma centers. *J Trauma Acute Care Surg*. 2012; **72**(4): 870-877. (Appendix B).

Conclusion

NTI has successfully completed a RFP, peer-review process, selection of four relevant trauma projects, and is conducting on-going management of the projects under this award.

The four studies funded through this award continue to work towards their potential to impact care and change current practices as they relate to coagulation, resuscitation and management of severe traumatic injuries, characterization of the effects of early sex-hormone environment following injury, and the development of targeted interventions to address hemorrhagic shock. Each of the funded projects remains of critical importance in the advancement in trauma care.

Abbreviations

AAST	American Association for the Surgery of Trauma
CeTIR	Center for Translational Injury Research
HRPO	Human Research Protection Office
HQDA	Headquarters Department of the Army
IRB	Institutional Review Board
NCE	No Cost Extension
NTI	National Trauma Institute
ORP	Office of Research Protections
OTSG	Office of the Surgeon General
RFP	Request for Proposal
UTHSCSA	University of Texas Health Science Center San Antonio
UCLA	University of California Los Angeles
UCSF	University of California San Francisco

Session IVB: Shock/Resuscitation/Infection
Paper 20 1:15 PM

THE PRINCIPAL COMPONENTS OF ACUTE TRAUMATIC COAGULOPATHY

Matthew Kutcher, Adam Ferguson, Mitchell Jay Cohen*, M.D., University of California, San Francisco Sponsor: Mitchell Jay Cohen*, M.D.

Invited Discussant**:** Sandro Rizoli

Introduction: Clotting factor abnormalities in acute traumatic coagulopathy are poorly understood, with application of traditional regression techniques confounded by collinearity. We hypothesized that principal components analysis (PCA), a pattern-finding technique, would identify clinically predictive patterns in the complex clotting factor milieu after trauma.

Methods: Plasma was prospectively collected from 163 critically-injured trauma patients. Prothrombin, Factors V, VII, VIII, IX, X, D-dimer, activated and native Protein C, and antithrombin III levels were assayed, and subjected to PCA to identify principal components (PCs).

Results: Of 163 patients, 19.0% had coagulopathy (INR≥1.3). PCA identified 3 PCs, accounting for 67.5% of variance (see Figure). PC1 identified global clotting factor depletion; PC2 the activation of Protein C and fibrinolysis; and PC3 Factor VII elevation and VIII depletion. PC1 score correlated with penetrating injury and injury severity, predicting coagulopathy (OR 4.67, p<0.001) and mortality (OR 1.47, p=0.032). PC2 score correlated with injury severity, acidosis, and shock, and significantly predicted ventilator-associated pneumonia (OR 1.59, p=0.008), acute lung injury (OR 2.24, p<0.001), multiorgan failure (OR 1.83, p=0.002), and mortality (OR 1.62, p=0.006). PC3 did not significantly predict outcomes.

	PC1	PC2	PC3
Prothrombin	-0.86	-0.04	0.11
Factor V	-0.78	0.01	-0.11
Factor VII	-0.62	0.01	0.47
Factor VIII	-0.35	0.34	-0.73
Factori IX	-0.69	0.07	0.03
Factor X	-0.88	-0.01	0.20
D-dimer	0.25	0.80	0.00
aPC	0.20	0.74	0.39
Protein C	-0.80	0.11	-0.05
AT III	-0.74	0.16	-0.17

Conclusion: PCA identifies distinct patterns of coagulopathy: depletion coagulopathy predicts mortality and INR elevation, while fibrinolytic coagulopathy predicts infection, end-organ failure, and mortality, without detectable differences in INR or PTT. These disparate patterns identify specific perturbations to target directed resuscitation and treatment.

AAST 2010 PLENARY PAPER

Moving from "optimal resources" to "optimal care" at trauma centers

Shahid Shafi, MD, MPH, Nadine Rayan, MHS, Sunni Barnes, PhD, Neil Fleming, PhD, Larry M. Gentilello, MD, *and* **David Ballard, MD, PhD, MSPH, FACP,** *Dallas, Texas*

BACKGROUND: The Trauma Quality Improvement Program has shown that risk-adjusted mortality rates at some centers are nearly 50% higher than at others. This "quality gap" may be due to different clinical practices or processes of care. We have previously shown that adoption of processes called core measures by the Joint Commission and Centers for Medicare and Medicaid Services does not improve outcomes of trauma patients. We hypothesized that improved compliance with trauma-specific clinical processes of care (POC) is associated with reduced in-hospital mortality.

METHODS: Records of a random sample of 1,000 patients admitted to a Level I trauma center who met Trauma Quality Improvement Program criteria (age ≥16 years and Abbreviated Injury Scale score ≥3) were retrospectively reviewed for compliance with 25 trauma-specific POC (T-POC) that were evidence-based or expert consensus panel recommendations. Multivariate regression was used to determine the relationship between T-POC compliance and in-hospital mortality, adjusted for age, gender, injury type, and severity.

RESULTS: Median age was 41 years, 65% were men, 88% sustained a blunt injury, and mortality was 12%. Of these, 77% were eligible for at least one T-POC and 58% were eligible for two or more. There was wide variation in T-POC compliance. Every 10% increase in compliance was associated with a 14% reduction in risk-adjusted in-hospital mortality.

CONCLUSION: Unlike adoption of core measures, compliance with T-POC is associated with reduced mortality in trauma patients. Trauma centers with excess in-hospital mortality may improve patient outcomes by consistently applying T-POC. These processes should be explored for potential use as Core Trauma Center Performance Measures. (*J Trauma.* 2012;72: 870–877. Copyright © 2012 by Lippincott Williams & Wilkins)

LEVEL OF EVIDENCE: II.

KEY WORDS: Trauma quality improvement; core measures; trauma processes of care.

Injured patients treated at designated trauma centers are more likely to survive than those treated at nondesignated hospitals.[1] However, Trauma Quality Improvement Program has demonstrated that risk-adjusted mortality rates are highly variable across designated trauma centers, with some centers achieving significantly better (or worse) outcomes than others.[2–5] The reasons for this variation are unclear. Donabedian principles of quality improvement suggest that structures and processes of care (POC) determine outcomes. Hence, if these centers have similar administrative and organizational structures ensured by their designation as trauma centers, there must be differences in patient care processes that result in variations in patient outcomes.

Variations in clinical practices across a spectrum of disease are well known. Extensive variations in clinical practices across and within trauma centers have also been reported.[6,7] For example, we have recently shown that risk-adjusted operative procedure rates for injuries to liver, spleen, and kidneys vary widely between trauma centers.[7] In addition, we found that centers that more frequently selected operative rather than nonoperative management of patients with the same severity of injury to these organs, and with the same hemodynamic status after injury, had significantly higher risk-adjusted mortality, suggesting that more is not always better. This was an example of a clinical process that both increased mortality and wasted precious healthcare resources. Hence, to ensure a high degree of clinical effectiveness and efficiency, it is necessary to identify clinical practices that are associated with best patient outcomes.

In an attempt to reduce variations in care and increase adoption of evidence-based practices, "core measures" were developed by the Centers for Medicare and Medicaid Services and the Joint Commission for the management of acute myocardial infarction, congestive heart failure, ventilator-associated pneumonia, and surgical care improvement (SCIP). Several studies suggest that compliance with core measures improves patient outcomes.[8] However, we have recently demonstrated that compliance with these measures, including SCIP, does not correlate with risk-adjusted outcomes of trauma patients.[9] Hence, there is a need to develop trauma-specific measures of best practices.

Submitted: January 5, 2011, Revised: November 7, 2011, Accepted: December 12, 2011.
From the Institute for Health Care Research and Improvement (S.S., N.R., S.B., N.F., D.B.), Baylor Health Care System, Dallas, Texas; and Division of Burn/Trauma/Critical Care (L.M.G.), Department of Surgery, University of Texas Southwestern Medical Center, Dallas, Texas.
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DOI: 10.1097/TA.0b013e3182463e20

The purpose of this study was to determine whether there were trauma-specific POC (T-POC) that may reduce mortality in trauma patients and to analyze the potential impact of improved adoption of T-POC on patient outcomes. The hypothesis for this study was that clinical care processes for management of trauma patients are variable and that improved compliance with T-POC was associated with reduced in-hospital mortality.

MATERIALS AND METHODS

This is a 3-year retrospective study (January 1, 2006 to December 31, 2008) of patients treated at a large, urban Level I trauma center, approved by the Institutional Review Board. During the study period, the trauma registry included 7,581 patients. Inclusion criteria consisted of the following:

1. Adults, defined as age ≥16 years.
2. Moderate to severe injuries defined as at least Abbreviated Injury Scale score ≥3 injuries.
3. Primary outcomes (in-hospital mortality, complications, and length of stay [LOS]) must be known.

Exclusion criteria consisted of the following:

1. Delayed admission defined as time from injury to arrival in emergency department (ED) ≥1 day.
2. Those deemed dead on arrival.
3. Gunshot wounds to the head or penetrating injuries outside the torso (torso defined as neck, chest, and abdomen).
4. Primary mechanism of injury of burns, poisoning, drowning, hanging, submersion, and asphyxiation.

Application of inclusion/exclusion criteria identified 2,242 patients. From these, 1,000 patients were chosen as the study population using a simple random methodology. Six patients were later eliminated due to incomplete information which could not be obtained. Thus, the final study population consisted of 994 patients. Any relevant information that was incomplete or missing in the registry data, such as date and time of admission, and certain laboratory values (specifically prothrombin time with international normalized ratio) were obtained from administrative databases or patient charts.

Trauma-Specific Processes of Care

Clinical guidelines from several professional groups were reviewed to select 25 T-POC for inclusion in this study (Appendix). These included the American College of Surgeons Committee on Trauma,[10] Eastern Association for the Surgery of Trauma,[11] Society for Critical Care Medicine,[12] the Brain Trauma Foundation,[13] the Glue Grant Consortium,[14] and the SCIP Project.[15] Because it was not possible to measure all care processes, only those that could directly impact outcomes of trauma patients and were measureable were selected. Selected T-POC encompassed all aspects of trauma care, including initial evaluation, resuscitation, operative care, critical care, rehabilitation, and injury prevention. We focused on four specific groups of patients: traumatic brain injuries (TBI), hemorrhagic shock (systolic blood pressure 90 mm Hg or less), pelvic fractures, and long bone extremity fractures (femur or tibia). TBI was chosen as it is the most common cause of death and disability in trauma patients, while hemorrhage is the second leading cause of death. Fractures were chosen as they represent a common injury in trauma patients. These fractures are an uncommon cause of death but are the second most common cause of disability after TBI.

Patient Eligibility

Information from the trauma registry dataset was used to identify patients who were eligible for each T-POC. Eligibility was determined by a combination of mechanism of injuries, specific injuries and severity, comorbidities, and procedures (Appendix). All data definitions were based on the National Trauma Data Standard Data Dictionary (NTDS, version 1.2.5) whenever possible.[16] Definition of complications was supplemented by our previous work.[17] In addition, definitions of the American Association for the Surgery of Trauma were used to identify solid organ injuries and related procedures.[18] Injuries were classified into blunt and penetrating based on the matrix of E-code groupings proposed by the Centers for Disease Control. Specific injuries, complications, and procedures were identified using ICD-9 codes which were validated by trauma registry staff. A software tool was developed that analyzed information contained in the trauma registry to identify patients who were eligible for T-POC. The accuracy of the tool in identifying patients eligible for T-POC was validated by manual review of registry data in a simple random sample of 72 patients (7% of the study population). For each T-POC, at least one patient who was deemed eligible and one who was deemed ineligible by the tool were identified and their trauma registry data were manually reviewed to determine whether they were correctly classified by the tool. If any discrepancy was identified, the tool was modified and revalidated until no further discrepancies were identified. After completion of the validation, the tool identified 774 patients (out of 994) who were eligible for at least one T-POC.

Data Collection

A written data dictionary was developed that defined each T-POC and a source hierarchy to determine whether patients received T-POC for which they were eligible. Four nurse abstractors reviewed electronic medical records after undergoing training on data abstraction guidelines. During training, each nurse abstractor reviewed the 10 patient charts. Discrepancies among reviewers were discussed and definitions were modified to minimize ambiguity during data abstraction. To further validate the quality of data abstracted, an independent nurse reviewer abstracted data from a 10% simple random sample of charts (82 patients). Inter-rater reliability was then calculated using kappa statistic. Inter-rater reliability was high (kappa >0.9), except for two T-POC whose definition was modified after initial data collection.

Data Analysis

The primary predictors of interest were the 25 T-POC. Patients who were eligible for each T-POC are reported as percentage of total study population. Patients who received each T-POC are reported as percentage of total number of patients who were eligible for that T-POC. Where relevant, times to T-POC from the time of arrival in ED are reported as medians.

For each patient, a compliance score was calculated based on the opportunity model used by Centers for Medicare and Medicaid Services for reporting compliance with their core measures.[9] For example, if a patient was eligible for 10 T-POC and received 8 of them, then his T-POC compliance score was 80. Similarly, if a patient was eligible for six T-POC and received all six, then his T-POC compliance score was 100. Primary outcome of interest was in-hospital mortality. Relationship between T-POC compliance score and risk-adjusted mortality was measured using logistic regression. Patients who were not eligible for any T-POC were excluded from this part of the analysis. Risk adjustment models included age; gender; mechanism of injury; injury severity score; first systolic blood pressure in ED; total Glasgow Coma Scale (GCS) in ED; and Abbreviated Injury Scale for injuries to head, chest, and abdomen. The final model for mortality was also used to estimate the number of lives that may be saved by improvements in compliance rates. Compliance score was also entered as a predictor in the model. All statistical analysis was performed using SAS (SAS Inc, Cary, NC).

RESULTS

Patient characteristics are summarized in Table 1 and reflect a typical urban trauma patient population. Median age was 41 years, 65% were men, 53% were Caucasians, 88% sustained a blunt mechanism, and 55% were uninsured. Overall in-hospital mortality was 12%, complication rate was 22%, and median LOS was 5 days. Of the study population, 774 patients (77%) were eligible for at least 1 of the 25 T-POC (Table 2). Of these, 197 (25%) were eligible for only one T-POC, 159 (21%) for two T-POC, 132 (17%) for three T-POC, and the rest of 286 (37%) were eligible for four or more T-POC. Compliance rates with various T-POC ranged from 10% to 99% (Table 2 and Fig. 1). Compliance in 90% or more eligible patients was achieved in only three T-POC: blood transfusion in hypotensive patients, endotracheal intubation with low GCS, and laparotomy for gunshot wounds to the abdomen. For patients who were eligible for at least one T-POC, the median Compliance Score was 60 (interquartile range, 29–100), suggesting that half of the patients only received 60% of the care they needed (Fig. 2). Less than a third of the patients had a 90% or higher compliance score (Fig. 2). In the multivariable model (controlling for all potential confounders listed in Methods section), there was a significant association between compliance score and mortality (odds ratio, 0.9862; 95% confidence interval, 0.9758–0.9967; $p = 0.01$) meaning that for every 1% increase in compliance score, the risk of mortality decreased by 1.38%. In other words, each 10% increase in compliance score was associated with an almost 14% reduction in risk-adjusted mortality. Hence, increasing compliance with these 25 POC from the observed rate of 57% to 100% has the potential to save 52 lives.

TABLE 1. Patient Characteristics and Crude Outcomes

Age (yr, Median With IQR)	**41 (27, 60)**
Male gender	65%
Blunt mechanism	88%
Ethnicity—minority	47%
Insurance—none, including Medicaid	54%
Injury Severity Score (median with IQR)	16 (10, 24)
Systolic blood pressure (mm Hg, median with IQR)	133 (114, 152)
Glasgow Coma Scale (median with IQR)	15 (14, 15)
Head injuries	49%
Chest injuries	46%
Abdominal injuries	28%
Mortality rate (crude)	12%
Complication rate (crude)	22%
Length of stay (d, median with IQR)	5 (3, 9)

IQR, interquartile range.

DISCUSSION

The findings of this study demonstrate large variations in clinical practices resulting in inadequate compliance with several commonly recommended clinical POC that are necessary for optimal management of trauma patients. These data also suggest that significant improvements in patient mortality may be achieved by improving compliance with these T-POC.

There are several implications of our findings. Trauma quality improvement efforts to date have focused on the availability of optimal resources. This approach has been highly successful as evidenced by the expansion of trauma systems and designated trauma centers. From 1991 to 2002, the number of trauma centers in the country has more than doubled, from 471 to 1,154.[19] Existing criteria for trauma center designation are based on expert consensus but not on patient outcomes. However, centers meeting these criteria have demonstrated improved outcomes.[1] Despite two decades of experience with trauma center designation process, it remains unclear which specific institutional structures and POC, or their combination, contribute to patient outcomes. In addition, designation criteria primarily focus on institutional structures with little emphasis on POC. The underlying assumption suggests that if resources are available, patients will receive the care they need. However, the findings of this study suggest otherwise. The results show that despite availability of adequate resources, almost half of the patients did not receive the care they should have. Hence, the focus of trauma quality improvement needs to shift from provision of "optimal resources" to provision of "optimal care."

Practice management guidelines have been developed by several professional societies and quality improvement forums to improve the quality of care. However, there has been little emphasis on measuring compliance with these guidelines which has resulted in inconsistent practices. Currently, there are no mechanisms in place to measure adoption of these guidelines in daily clinical practices. Hence, our observations are not surprising. The overall median compliance score of 60 is consistent with previous reports on management of other acute and chronic diseases showing that, on average, Americans receive about half of recommended medical care processes.[20] For example, it has been shown that less than half of patients with acute myocardial infarction who were eligible for thrombolytic therapy received it during hospitalization.[21] Only 45% of patients who suffered heart attacks received beta-blockers, whereas only 28% smokers received advice on smoking cessation. Never-

TABLE 2. Process of Care

Process	Eligible Number (%)	Compliant Number (%)	Inter-Rater Agreement (Kappa)	Time to Process (Median)
Head CT scan	295 (30)	218 (74)	1.00	16 min
CT angiography neck for blunt cerebrovascular injuries	262 (26)	37 (14)	0.97	
PRBC transfusion	117 (12)	116 (99)	0.92	16 min
Blood gas measurement	117 (12)	72 (62)	1.00	11 min
Endotracheal intubation	90 (9)	86 (96)	0.93	5 min
FFP or PCC	37 (4)	15 (41)	0.24*	5 h
ED thoracotomy	8 (<1)	2 (25)	1.00	
Laparotomy in abdominal gunshot wounds	11 (1)	10 (91)	1.00	39 min
Laparotomy in blunt abdominal trauma	20 (2)	10 (50)	Too few to evaluate	51 min
External pelvic compression (binder, sheet, other devices) in ED	23 (2)	6 (26)	1.00	34 min
Angioembolization	23 (2)	4 (17)	1.00	2 h
Preoperative antibiotics	83 (8)	68 (82)	1.00	
Craniotomy	74 (7)	11 (15)	1.00	3.5 h
Intracranial pressure monitor	100 (10)	10 (10)	1.00	5.5 h
I&D in operating room	17 (2)	10 (59)	1.00	3 h
Intravenous antibiotics	17 (2)	15 (88)	1.00	1 h
Definitive fracture fixation	89 (9)	78 (89)	1.00	Day 1
Operative pelvic fixation	94 (9)	38 (40)	1.00	Day 2
Initiation of DVT prophylaxis (chemical or filter)	224 (22)	145 (65)	1.00	Day 2
Initiation of nutrition (Enteral or TPN)	276 (28)	194 (70)	1.00	Day 3
Low stretch ventilation (≤6 mL/kg)	0	NA	NA	
VAP—specimen obtained before antibiotic use	45 (5)	39 (87)	1.00	
SBI before discharge from hospital	322 (32)	143 (44)	0.970	
Physical therapy/rehabilitation evaluation	138 (14)	96 (70)	1.00	Day 2
Abdominal CT scans for blunt solid organ injuries	121 (12)	92 (76)	0.48*	

ARDS, acute respiratory distress syndrome; CT, computed tomography; DVT, deep venous thrombosis; FFP, fresh frozen plasma; I&D, irrigation and debridement; INR, international normalized ratio; IRR, inter-rater reliability; PCC, prothrombin complex concentrate; PRBC, packed red blood cells; SBI, alcohol screening and brief intervention; SBP, systolic blood pressure; TPN, total parenteral nutrition; VAP, ventilator-associated pneumonia.

* Eligibility criteria for these process measures were modified in the data entry tool during the chart review. Kappa calculations did not account for these modifications.

theless, some of the deficits in delivery of trauma care that are identified in this study are truly astounding, especially considering the fact that the study focused on basic clinical practices in trauma care, not cutting-edge research. For example, only half of the patients with severe blunt abdominal injuries who were hypotensive underwent a laparotomy. Over a third of the patients with open fractures of femur and tibia did not undergo an operative irrigation and debridement of their fractures. Only a quarter of patients with pelvic fracture who were hypotensive received external pelvic compression. Nine of 10 patients with documented intracranial injury on computed tomography and a low GCS who were intubated were managed without an intracranial pressure monitor. Lack of provision of basic clinical care reflects a significant quality gap. In addition, variable practice patterns result in over- or underutilization of specific therapies and increase healthcare costs with no improvement in patient outcomes.[21]

It is clear that the availability of "optimal resources" does not ensure delivery of "optimal care." Delivery of optimal care requires translation of scientific knowledge into everyday practice.[22] It is a complex process with several interacting components. Hence, it is unlikely that a single intervention can improve clinical practices. Clearly, it is important to monitor and report compliance with common clinical processes. The use of standardized order sets and computerized decision support systems has been shown to improve compliance with recommended POC.[23,24] Another approach is the use of checklists.[25] A checklist of clinical care processes that a patient is eligible for based on his injuries and injury severity may enable providers to monitor these processes at the bedside regularly and use them as a performance improvement tool. Further multi-institutional studies, and perhaps interventional trials, need to be undertaken to identify best POC at trauma centers. The resultant set of POC, when viewed together, will permit a robust assessment of quality of care provided to injured patients. These processes, which may be called Trauma Core Measures, will maximize the patients' likelihood of survival, minimize the risk of complications, and may reduce healthcare resource utilization. In addition, the findings will spur coalitions of stakeholders to improve the quality of care across all trauma centers and may be used to improve the criteria used for verification and designation of trauma centers.

This study has a few limitations that must be acknowledged. It is a retrospective analysis with all its inherent limitations. The findings reflect the experience of a single

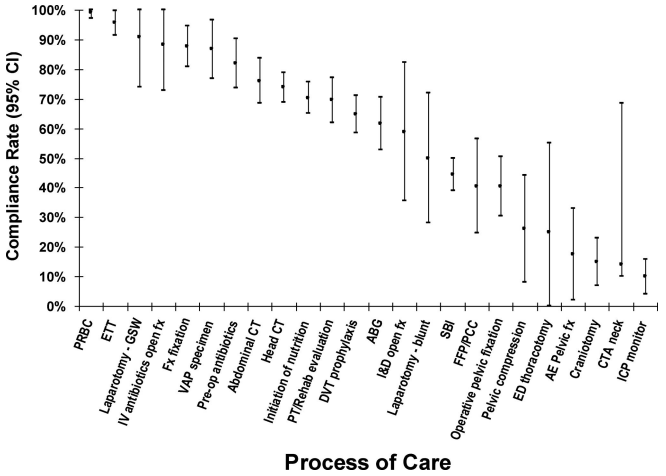

Figure 1. Compliance rate (percentage with 95% confidence interval). ABG, arterial blood gas; AE, angioembolization; CT, computed tomography; CTA, computed tomographic angiography; DVT, deep venous thrombosis; FFP, fresh frozen plasma; ETT, endotracheal tube; Fx, fracture; ICP, intracranial pressure; I&D, irrigation and debridement; IV, intravenous; PCC, prothrombin complex concentrate; PRBC, packed red blood cells; PT, physical therapy; SBI, alcohol screening and brief intervention; VAP, ventilator-associated pneumonia.

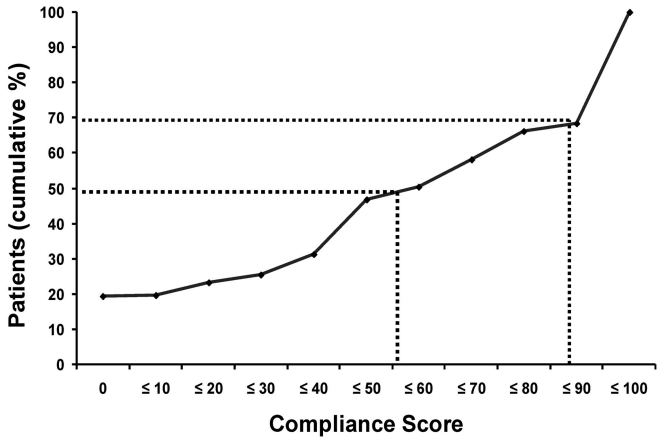

Figure 2. Compliance score.

urban institution with its own unique characteristics. Compliance with specific processes was determined based on the documentation provided in the charts, and lack of documentation may not mean lack of compliance. In addition, we were not able to analyze the reasons for noncompliance. For example, it is possible that patients who were eligible for endotracheal intubation but did not undergo intubation might have been designated as do not resuscitate or may have had sustained nonsurvivable injuries in which case the intervention would be futile. Because of these reasons, it is probably safe to say that "optimal" care may not necessarily mean 100% compliance. Large multicenter studies are needed to define "acceptable" or "optimal" compliance rate for each specific process. The study did not have enough power to determine specific clinical processes that were independent predictors of patient outcomes. Nor was the study design appropriate to determine the impact of specific interventions on patient outcomes as that would require a randomized controlled trial. In other words, our findings do not identify "best practices" in trauma. However, they do suggest that compliance with currently recommended care has the potential to improve patient outcomes but that needs to be proven in a prospective study. The processes studied were chosen by the study investigators only. An important consideration in the selection process was our ability to obtain information in a retrospective chart review within the resources available. It is possible that a longer list of processes may be more appropriate to measure the quality of care. It should be noted that McGlynn et al. [20] measured an average of 15 processes per patient whereas we measured 25 processes in this study. Moreover, the purpose of this study was not only to validate which POC work the best but also to determine whether our practices were consistent with published guidelines. We would also like to emphasize that although the statistical analysis suggests that additional lives could be saved with increased compliance with T-POC, we do not know the causes of death in this patient population. In fact, peer review during this time period did not find any preventable or potentially preventable deaths. Thus, impact on mortality and other outcomes, such as complications, costs, and LOS, needs further study. However, we think that this discrepancy provides further impetus to elucidate details of care provided to the patients, especially given our finding of improvement in patient outcomes associated with increased compliance with recommended care. A more detailed analysis of how the care is delivered to individual patients using a structured and standardized approach based on current practice guidelines will make the peer review process more informative.

In conclusion, the findings of this study demonstrate that compliance with several generally recommended clinical processes for management of patient with moderate to severe traumatic injuries remains inadequate. Improved compliance with these processes has the potential to significantly reduce mortality. The focus of quality improvement in trauma care needs to shift from "optimal resources" to "optimal care." In short, we can do better.

AUTHORSHIP

S.S., N.R., and N.F. designed this study. S.S., N.R., and S.B. collected and analyzed the data. All authors participated in manuscript preparation.

DISCLOSURE

Supported in part by the Agency for Healthcare Research and Quality (AHRQ grant no. 1R01HS017718–01A1) and the Seeger Foundation of the Baylor University Medical Center, Dallas, Texas. Funded by Award # NTI-NTI-TRA-10-020 from the National Trauma Institute and sponsored by the Department of the Army, Prime award #W81XWH-11-1-0841. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

APPENDIX

TABLE A1. Processes of Care

Care Aspect	Process	Eligible Patients
1. Initial evaluation	Head CT scan	Blunt mechanism AND GCS score <15 upon initial assessment
2. Initial evaluation	CT angiography neck for blunt cerebrovascular injuries	Blunt mechanism AND any one of the following fractures Le Forte II or III facial OR cervical spine OR base of skull
3. Resuscitation	PRBC transfusion	Hypotensive (SBP ≤90 mm Hg) upon arrival
4. Resuscitation	Blood gas measurement	Hypotensive (SBP ≤90 mm Hg) upon arrival
5. Resuscitation	Endotracheal intubation	GCS score ≤8 upon initial assessment
6. Head injuries	FFP or PCC	Intracranial bleed AND INR ≥1.5
7. Resuscitation	ED thoracotomy	Pulse present upon arrival AND died in ED
8. Hemorrhage control	Laparotomy in abdominal gunshot wounds	Gunshot wound abdomen AND SBP ≤90 mm Hg AND any abdominal injury
9. Hemorrhage control	Laparotomy in blunt abdominal trauma	Blunt mechanism AND SBP ≤90 mm Hg AND Abdominal AIS score ≥4
10. Hemorrhage control	External pelvic compression (binder, sheet, other devices) in ED	Pelvic fracture AND SBP ≤90 mm Hg
11. Hemorrhage control	Angioembolization	Pelvic fracture AND SBP ≤90 mm Hg
12. Operative care	Preoperative antibiotics	Patients undergoing laparotomy
13. Head injuries	Craniotomy	GCS score ≤8 AND intracranial bleed on head CT
14. Head injuries	Intracranial pressure monitor	GCS score ≤8 AND intracranial bleed on head CT AND endotracheal intubation
15. Fracture management	I&D in operating room	Open fracture femur OR tibia
16. Fracture management	Intravenous antibiotics	Open fracture femur OR tibia
17. Fracture management	Definitive fracture fixation	Open or closed fracture femur OR tibia AND not in ICU
18. Fracture management	Operative pelvic fixation	Operative pelvic fracture AND no intracranial bleed AND no acute lung injury
19. Critical care	Initiation of DVT prophylaxis (chemical or filter)	No Intracranial bleed AND any one of the following: femur fracture, tibia fracture, intubated
20. Critical care	Initiation of nutrition (Enteral or TPN)	Intubated patients
21. Critical care	Low stretch ventilation (≤6 mL/kg)	ARDS
22. Critical care	VAP—specimen obtained before antibiotic use	Pneumonia AND intubated
23. Injury prevention	SBI before discharge from hospital	Nondependent drug use
24. Rehabilitation	Physical therapy/rehabilitation evaluation	Fracture femur OR tibia OR pelvis AND not in ICU
25. Evaluation	Abdominal CT scans during hospital stay	Patients with blunt injuries to liver, spleen, kidneys managed nonoperatively

ARDS, acute respiratory distress syndrome; CT, computed tomography; DVT, deep venous thrombosis; FFP, fresh frozen plasma; I&D, irrigation and debridement; INR, International Normalized Ratio; IRR, inter-rater reliability; PCC, prothrombin complex concentrate; PRBC, packed red blood cells; SBI, alcohol screening and brief intervention; SBP, systolic blood pressure; TPN, total parenteral nutrition; VAP, ventilator-associated pneumonia.

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DISCUSSION

Dr. Mark R. Hemmila (Ann Arbor, Michigan): Dr. Shafi and co-authors have presented excellent work in examining the trauma-specific processes of care and their ability to reduce in-hospital mortality.

The take-home point of this paper is that for every percentage increase in compliance with these processes of care, they found a 14% reduction in mortality.

I'm a firm believer that the more we can reduce unnecessary variation in care, the more likely we are to see improved results for our patients, keeping in mind that there will always be occasional exceptions to these processes based on circumstances.

Examining processes of care and also performance of external data validation represent two difficult but necessary areas for TQIP in which much heavy lifting will be required.

Digging a little deeper, the most striking result to me was the wide variation in compliance with these trauma specific processes of care. Specifically, rates of compliance were low for ICP monitor and craniotomy of brain injured patients and were also low for pelvic compression and angioembolization in pelvic fracture patients. Is this because the software algorithm identified patients with a set of injuries that suggests the potential for intervention but in reality intervention would be futile (i.e. a bad brain injury in an elderly patient) or is it reflective of lapses in optimal care? Along these lines, I have the following three questions:

First, your results suggest that within a trauma system there are still many patients with preventable or potentially preventable mortality. For the same cohort do you have any data on how many patients were peer reviewed and found to be within this category?

Secondly, there may be factors why aggressive neurosurgical intervention was not pursued. For example a patient may appear to be a candidate for life saving intervention but the surgeons and family are concerned about a non-functional outcome. Does this explain low compliance with the use of neurosurgical interventions?

And third, is there a subgroup of three to five processes of care from your study when applied prospectively would potentially result in improved outcomes? In other words, which of these trauma-specific processes of care when followed is likely to have the greatest impact?

Thank you for the opportunity to discuss this paper. I think this is excellent work. It involves a lot of nitty-gritty digging into the data. I look forward to more work from Dr. Shafi on this topic.

Dr. Ajai K. Malhotra (Richmond, Virginia): I really enjoyed that work and the presentation. But I'm curious, is this trauma center maybe not a good trauma center? Did you go back and look at the caterpillar curve from the TQIP data to see where it stood? Is it one of the higher-performing centers, lower-performing centers, or intermediate centers?

Dr. Walter Biffl (Denver, Colorado): It's a nice presentation, but for those of us who do work in quality in our institutions, we're all well aware of the shortcomings of the administrative data bases.

While a TQIP is certainly a rigorous one, my primary question is how are you proposing that these data be used?

I mean, looking at the low compliance factors on your list, there is certainly not consensus among those in this room or among large organizations how ED thoracotomy should be applied, who should be screened for cerebrovascular injury, who should have pelvic angioembolization, etc. So you need to be careful about publishing these data and saying a center is not doing their job if they're not complying with certain measures.

Dr. Thomas J. Esposito (Maywood, Illinois): I was just wondering if any of the particular compliance violations were anymore egregious than others with regard to mortality? And, secondly, did you assess the impact on morbidities as well?

Dr. Carnell Cooper (Baltimore, Maryland): In the last statement in your abstract, you suggest that trauma centers of excess mortality may improve with application of this process. Does it suggest that only if you have excess mortality this is helpful? Is it not helpful in improving if you are from an average trauma center?

Dr. Shahid Shafi (Grapevine, Texas): That wasn't so bad, actually. Dr. Hemmila asked me three questions:

How many of these deaths were preventable? Now, let me preface my answer – and I have five minutes I can go on – that this study has, of course, certain limitations. This is a single center experience. And we all know that the practices vary from institution to institution and from within an institution from surgeon to surgeon.

In fact, I was looking at the program. There are at least two other papers, one is by Dr. Hoyt who is going to talk

about the variation in practices for DVT screening, and there was another paper which talks about variation in practices about pain management for rib fractures. So those variations are common.

What I showed is a reflection of a single center, but the data are quite compelling, especially the relationship between the compliance with processes and the outcomes.

How many of these deaths were preventable? During the same three year period, there were 500 or close to 600 deaths at the trauma center. Only 17 of those deaths were classified as potentially preventable. The rest of them were classified as non-preventable. Now, but we all know that at some point every death becomes inevitable. And this is actually the talk of another paper. Here we will talk about the failure to rescue.

So if you have complication, you fail to rescue and then the patient inevitably goes into multiple organ failure and dies, is that a non-preventable death? So I think that we need to look at that classification more carefully.

Low compliance with neurosurgical interventions is pretty obvious in our data set. In every trauma center that I have worked at, that has always been discussed between trauma surgeons and neurosurgeons as to what needs to be done. The Brain Trauma Foundation Guidelines look pretty clear to us, but they don't look as clear to neurosurgeons. So, all I can say is that just reflects local practices. I don't know why. In this retrospect analysis we were not able to identify the causes of why certain things were not done.

A critical question that you asked, and I think Dr. Esposito also asked the same question, is which of these 25 processes of care are the critical ones? Well, again, I think the concept that I am trying to convey is that there is no magic bullet. I think what we have to do is provide good quality care day in and day out. And that requires going through multiple processes and making sure that every one of them is crossed.

I think that the 25 processes that were chosen should be looked at simply as an indicator of the quality of care – not that DVT prophylaxis will save life but if you're doing DVT prophylaxis diligently in more than 90% of your patients you are probably doing everything else right too.

So in this particular data set, we did not have the power to identify which specific processes of care are associated with mortality. Now, we have recently received funding from National Trauma Institute to expand the study to three centers and hopefully in a couple of years we will be able to give you some more information.

Dr. Malhotra asked if this is a poorly-performing trauma center. Dr. Peitzman, what can I say? I mean, I guess I'm up here and I'm willing to say that we are not doing as well as we think we are. The question is, are you willing to do the same? But this particular center is actually, I don't know their OT ratio. They are not a participant in TQIP, yet. But they obviously allowed me access to their data.

Dr. Biffl asked about the specific processes of care. I totally agree with you. There is no consensus on which processes actually matter. But, again, I think concept is to look at compliance as an indicator of quality of care and not an end in itself.

The last question Dr. Esposito asked was have you looked at morbidities? We have started looking at morbidities but our analysis is still quite preliminary. And it actually seems like the more lives you save the complications go up. So the increase in compliance seems to be associated with the increase in complication rates and length of stay, but we are not sure about that yet.

I'm missing the last question. This was about improvements. Which process is more important? I already addressed that. Oh, yes, how would you use it? The reason I started looking at it is because if TQIP tells a center that you're not doing well, we must also tell them what you can do to improve yourself. So this was an example of what can be done to improve yourself. But certainly every center will probably improve their outcomes based on better compliance.